

**COMMONWEALTH OF MASSACHUSETTS  
Board of Registration in Pharmacy**

**NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE  
BOARD OF REGISTRATION IN PHARMACY**

February 6, 2020  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Yulanda Kiner, Phone: 617-624-5848 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>
	<b>II</b>	<b>APPROVAL OF AGENDA</b>
<b>8:40</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of January 9, 2020 Regular Session Minutes</li> <li>• Introduction of Interns: <ul style="list-style-type: none"> <li>➤ Hemali Patel – Northeastern University</li> <li>➤ Sara Panahi - Northeastern University</li> </ul> </li> </ul>
<b>8:45</b>	<b>IV</b>	<b>REPORTS</b> <ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> <li>• Monthly report from probation</li> <li>• Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> <li>• PSUD Report-Policy 17-03</li> </ul>
<b>8:50</b>	<b>V</b>	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>• Genoa Healthcare/Milford: New Community Pharmacy</li> <li>• ETHOS Veterinary Health; DS90035 – Renovation</li> <li>• Bravo Pharmacy; DS89981 – Renovation</li> <li>• Winn Pharmacy – New Community Pharmacy</li> <li>• Roula Barada; PH232382 – Reactivation of Pharmacist license</li> <li>• Williamstown Apothecary – New Community Pharmacy</li> <li>• Walmart Pharmacy 10-2366 – Change of Manager</li> </ul>

<b>9:50</b>	<b>VI</b>	<b>POLICIES and ADVISORIES</b> <ul style="list-style-type: none"> <li>• Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle</li> <li>• Policy 2020-02: Compounding of Commercially Available Drugs</li> <li>• Staff Action Policy 13-01: Licensure Applications and Notices</li> </ul>																		
<b>10:15</b>	<b>VII</b>	<b>REGULATIONS</b> <ul style="list-style-type: none"> <li>• Review of technical and grammatical changes for: <ul style="list-style-type: none"> <li>➢ 247 CMR 6.00: Licensure of pharmacies</li> <li>➢ 247 CMR 9.00: Professional practice standards</li> <li>➢ 247 CMR 15.00: Continuous quality improvement program</li> <li>➢ Update 247 CMR 20.00: Reporting</li> </ul> </li> <li>• Initial Review of CMR 13.00: Registration requirements and minimal professional standards for nuclear pharmacies</li> </ul>																		
<b>11:15</b>	<b>VIII</b>	<b>FILE REVIEW</b> <table border="1"> <tr> <td><b>1</b></td> <td>SA-INV-15665</td> <td>Walgreens #3135, DS2289</td> </tr> <tr> <td><b>2</b></td> <td>SA-INV-15664</td> <td>Walgreens #9152, DS3515</td> </tr> <tr> <td><b>3</b></td> <td>PHA-2019-0115</td> <td>Walgreens #2268, DS1901</td> </tr> <tr> <td><b>4</b></td> <td>PHA-2019-0113</td> <td>Rite Aid #10206, DS2412</td> </tr> <tr> <td><b>5</b></td> <td>PHA-2019-0112</td> <td>Stop &amp; Shop #20, DS2669</td> </tr> <tr> <td><b>6</b></td> <td>PHA-2019-0106</td> <td>Eaton Apothecary #2300, DS89842</td> </tr> </table>	<b>1</b>	SA-INV-15665	Walgreens #3135, DS2289	<b>2</b>	SA-INV-15664	Walgreens #9152, DS3515	<b>3</b>	PHA-2019-0115	Walgreens #2268, DS1901	<b>4</b>	PHA-2019-0113	Rite Aid #10206, DS2412	<b>5</b>	PHA-2019-0112	Stop & Shop #20, DS2669	<b>6</b>	PHA-2019-0106	Eaton Apothecary #2300, DS89842
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<b>12:30</b>	<b>LUNCH BREAK</b>																			
<b>1:30</b>	<b>IX</b>	<b>EXECUTIVE SESSION</b> The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to consider a violation of probation, and to evaluate the Good Moral Character as required for registration for pending applicants.																		
<b>2:00</b>	<b>X</b>	<b>ADJUDICATORY SESSION(M.G.L. ch. 30A, §18)</b>																		
<b>2:30</b>	<b>XI</b>	<b>M.G.L. c. 112, § 65C SESSION</b>																		
<b>5:00</b>	<b>XII</b>	<b>ADJOURNMENT</b>																		

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY**

**MINUTES OF THE GENERAL SESSION  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts, 02114  
February 6, 2020**

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**Board Members Present**

Kim Tanzer, PharmD, RPh. President  
Julie Lanza, CPhT, President Elect  
Patrick Gannon, RPh  
Sebastian Hamilton, Pharm D, RPh  
Dr. Richard Lopez, MD  
Andrew Stein, Pharm D  
Timothy Fensky, RPh  
Stephanie Hernandez, Pharm D, BCGP, RPh  
Carly Jean-Francois, RN, NP  
Michael Godek, RPh

**Board Members Not Present**

Leah Giambarresi, Pharm D, RPh, Secretary  
Susan Cornacchio, JD, RN  
Dawn Perry, JD

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, Assistant Executive Director  
Heather Engman, JD, Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
Michelle Chan, RPh Quality Assurance Pharmacist  
Joanne Trifone, RPh, Director of Investigator  
Gregory Melton, Pharm D, JD, RPh Investigator  
Christina Mogni, RPh Investigator  
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor  
Joanna Chow, Office Support Specialist  
Richard Harris, Program Analyst

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**TOPIC I.** Attendance by roll call:

**CALL TO ORDER 8:32 AM**

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; A. Stein, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; T. Fensky, yes; R. Lopez, yes.

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**Topic II.**

**Approval of Agenda**

**TIME 8:34 AM**

**Agenda February 6, 2020**

**DISCUSSION:**

Change to Agenda:

1. none

**ACTION:**

Motion by M. Godek, seconded by C. Jean-Francois and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves and also introduces the NEU Boston Interns on APPE rotation: Hemali Patel and Sara Panahi

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:35 AM**

**Minutes**

**1. Draft 1/9/20 General Session Minutes**

No noted Changes.

**Action:**

Motion by S. Hamilton, seconded J. Lanza, and voted unanimously to approve the regular session minutes of 1/9/20 with noted changes.

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**TOPIC IV**

**REPORTS**

**Applications approved pursuant to Licensure Policy 13-01**

**Time: 8:36 AM**

**Discussion:** M. BOTTO reported that there were twenty (20) Change of Managers applications approved pursuant to Licensure Policy 13-01.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from Probation**

**Time: 8:36 AM**

**Discussion:** M. BOTTO provided the January 8, 2020 – January 29, 2020 Pharmacy Board Probation Monthly Report, which noted that two (2) licensees satisfactorily completed probations, one (1) given the opportunity to cure, one (1) extension granted and there are currently twenty-nine (29) licensees on probation.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from BDR pursuant to Policy 14-02**

**Time: 8:36 AM**

**Discussion:** M. BOTTO noted that there was one (1) Board Delegated Review case heard on February 3, 2020. There was one Consumer grievance (SA-INV-15827) which was closed with no violation. The Board

Delegated Review session was attended by K. TANZER as the Board President, W. FRISCH Director of Pharmacy Compliance (by phone,) H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

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<b>TOPIC IV</b>	<b>REPORTS</b>	
<b>Above Action Levels Approved by Staff Action 16-04</b>		<b>Time: 8:37 AM</b>

**Discussion:** M. BOTTO noted that zero (0) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

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<b>TOPIC IV</b>	<b>REPORTS</b>	
<b>PSUD Report by Staff Action 17-03</b>		<b>Time: 8:37 AM</b>

**Discussion:** E. TAGLIERI noted that in January 2019, there were two (2) inquiries, four (4) admissions and fourteen (14) active participants.

So noted

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<b>TOPIC V</b>	<b>APPLICATIONS</b>	
<b>1. Genoa Healthcare/Milford</b>	<b>New Community Pharmacy</b>	<b>TIME: 8:39 AM</b>

REPRESENTED BY: Kevin O'Connell (Director of Operations)

RECUSAL: NONE

DISCUSSION: Genoa Healthcare currently has 12 pharmacy locations in Massachusetts. This pharmacy will be a 400-square foot pharmacy located in a clinic in Milford, MA. The same waivers that were applied to the previous pharmacies are applicable here.

ACTION: Motion by A. STEIN, seconded by P. GANNON, voted unanimously by those present to approve the application for a new community pharmacy pending a successful inspection.

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<b>2. ETHOS Veterinary</b>	<b>Renovation</b>	<b>TIME: 8:41 AM</b>
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REPRESENTED BY: W. FRISCH

RECUSAL: NONE

DISCUSSION: ETHOS Veterinary submitted an application for renovation to convert a USP <797> sterile compounding room into a USP <800> compliant room for USP<795> hazardous non-sterile compounding. It was approved through staff action. In 2018, ETHOS Veterinary came to the Board with plans for a non-sterile compounding area with a hazardous room but renovations did not occur.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, voted unanimously by those present to approve the application for renovation.

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**3. Bravo Pharmacy DS8981**

**Renovation**

**TIME: 8:43 AM**

REPRESENTED BY: Eris Karanxha (MOR,) David Trinks (Consultant)

RECUSAL: NONE

DISCUSSION: Bravo Pharmacy submitted an application to renovate the current compounding area to accommodate non-sterile and non-sterile hazardous compounding with a separate USP <800> compliant room.

W. FRISCH reached out to USP and USP recommended separate rooms for non-sterile and hazardous compounding.

T. FENSKY asked if there is a door separating the non-sterile and hazardous compounding. MOR clarified that there is a door with self-closure separating the two rooms. Both rooms will be negative pressure and compound only non-sterile products in both rooms (non-sterile and non-sterile hazardous)

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, voted unanimously by those present to approve the application for renovation.

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**4. Winn Pharmacy**

**New Community Pharmacy**

**TIME: 8:47 AM**

REPRESENTED BY: Quynh Quach (MOR,) Paul Garbarini (Attorney)

RECUSAL: NONE

DISCUSSION: Quynh Quach presents before the Board to request approval for a new community pharmacy in Lowell, MA. Winn Pharmacy will be a retail pharmacy that partakes in moderate non-sterile compounding. The first floor of the building consists of the retail store and pharmacy, the second floor is residential housing where the MOR resides. D. SENCABAUGH reiterated that the pharmacist must close the pharmacy for lunch because the regulation mandates a maximum 12-hour day for pharmacists and Winn Pharmacy would be open for 12.5 hours. Quynh Quach successfully answered all other questions from Board members pertaining to past pharmacy experience and activities of the pharmacy.

ACTION: Motioned by S. HAMILTON, seconded by M. GODEK, voted unanimously by those present to approve the application for new community pharmacy pending a successful inspection.

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**5. Roula Barada; PH232382**

**Reactivation of RPh License**

**TIME: 8:58 AM**

REPRESENTED BY: Roula Barada

RECUSAL: NONE

DISCUSSION: Roula Barada presents before the Board to request reactivation of her pharmacy license. She went back to Lebanon in 2013 after working at Walgreens for 5 years. She kept up with her CE requirements until 2017 due to family issues and then moved back to the states recently due to her husband's job.

P. GANNON asked if her CEs are currently completed and up to date and they are.

ACTION: Motioned by P. GANNON, seconded by S. HERNANDEZ, voted unanimously by those present to approve reactivation of pharmacist license pending successful completion of MPJE.

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**6. Williamstown Apothecary**

**New Community Pharmacy**

**TIME: 9:01 AM**

REPRESENTED BY: David Dupee (MOR), Keith Preston (Director of Pharmacy) and David MacHaffie (Outpatient Pharmacy Director)

RECUSAL: NONE

DISCUSSION: David Dupee presents before the Board, along with two directors from Berkshire Health System, to request approval for a new community pharmacy in Williamstown, MA.

This pharmacy is the first stand alone, for profit, pharmacy under Berkshire Health System. The pharmacy will be located in the middle of Williamstown College in order to serve the student and staff of the college.

P. GANNON suggested compounding both simple and moderate compounding products (as opposed to simple compounding only per application.)

ACTION: Motioned by S. HAMILTON, seconded by C. JEAN-FRANCIS, voted unanimously by those present to approve the application for new community pharmacy pending successful inspection and amend application to include simple and moderate compounding.

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**7. Walmart Pharmacy 10-2366 DS3400**

**Change of Manager**

**TIME: 9:08 AM**

REPRESENTED BY: Brandon Cherenzia (MOR)

RECUSAL: NONE

DISCUSSION: Brandon Cherenzia presents before the Board to request approval for a change in manager at Walmart Pharmacy located in North Attleboro, MA. Brandon has worked for Walmart since 2003 and was previously MOR in Rhode Island. He has worked in the North Attleboro store since 2017.

K. TANZAR reiterated the importance of maintaining staff ratio now that Brandon in Manager of Record.

ACTION: Motioned by A. STEIN, seconded by P. GANNON, voted unanimously by those present to approve the application for change of manager.

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**TOPIC VI****Policies and Advisories****1. Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle****Time: 9:11 AM****Presented by:** M. CHAN and W. FRISCH**Recusal:** None

**Discussion:** This policy updates and replaces policy 2012-03 and is intended for pharmacists whose licenses have lapsed beyond one renewal cycle. It does not apply to pharmacist licenses that have been revoked or suspended. Retaking the MPJE remains a requirement. The Board would still have discretion as to whether retraining and/or retaking NAPLEX would be necessary for those pharmacists who have not been recently employed in a pharmacist role.

**Action:** Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present to approve Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle.

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**2. Policy 2020-02: Compounding of Commercially Available Drugs****Time: 9:13 AM****Presented by:** M. CHAN and W. FRISCH**Recusal:** None

**Discussion:** This policy replaces the current Board advisory and outlines the state requirements for compounding, including veterinary compounding. Although federal law only restricts pharmacies from compounding any drug that is essentially a copy of a commercially available drug “regularly or in inordinate amounts”, state law is stricter.

The policy refers to the FDA guidance document on copies of commercially available drugs and adopts the FDA’s positions on what is considered a commercially available drug, what is essentially a copy of a commercially available drug, and how they define “significant differences”.

The main policy points reiterate the requirements for:

- a patient specific prescription
- meeting a significant unique medical need (i.e. removal of a dye)
- and having documentation of that medical need.

T. FENSKY asked how the unique medical should be documented. M. CHAN clarified that is up to the pharmacy how it should be documented; the only requirement that it be documented.

**Action:** Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by those present to approve Policy 2020-02: Compounding of Commercially Available Drugs.

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**3. Staff Action Policy 13-01: Licensure Applications and Notices****Time: 9:14 AM****Presented by:** M. CHAN and W. FRISCH



**Recusal:** None

**Discussion:** M. CHAN presented changes to this policy that would limit the staff's ability to extend a pharmacy technician trainee's license only once, up to one year.

The specific nuclear pharmacist requirements have been removed and the policy now just defers to the requirements in the nuclear regulations.

The application for new or relocated drug stores was updated to require two staff members, including the associate executive director, to review all applications as a safety / double check similar to other sections of the policy.

Applications for remodeling chain store pharmacies tend to have similar layouts and changes, so a separate section was added to clarify the approval process in these situations.

**Action:** Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by those present to approve Staff Action Policy 13-01: Licensure Applications and Notices.

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**TOPIC VII**

**Regulations**

**1. 247 CMR 6.00 Licensure of Pharmacies**

**Time: 9:16 AM**

**Presented by:** H. ENGMAN

**Recusal:** None

**Discussion:** H. ENGMAN presented a review of the administrative technical and grammatical changes to 247 CMR 6.00 Licensure of Pharmacies.

**Action:** Motion by P. GANNON, seconded by S. HAMILTON, and voted unanimously by those present to adopt the changes and move forward with promulgation.

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**2. 247 CMR 9.00 Professional Practice Standards**

**Time: 9:19 AM**

**Presented by:** H. ENGMAN

**Recusal:** None

**Discussion:** H. ENGMAN presented a review of the administrative technical and grammatical changes to 247 CMR 9.00 Professional Practice Standards.

**Action:** Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present to adopt the changes and move forward with promulgation.

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**3. 247 CMR 15.00 Continuous Quality Improvement Program**

**Time: 9:19 AM**

**Presented by:** H. ENGMAN

**Recusal:** None

**Discussion:** H. ENGMAN presented 247 CMR 15.00 Continuous Quality Improvement Program with no administrative revisions.

**Action:** Motion by P. GANNON, seconded by J. LANZA, and voted unanimously by those present to move forward with promulgation.

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**4. 247 CMR 20.00 Reporting**

**Time: 9:20 AM**

**Presented by:** H. ENGMAN

**Recusal:** None

**Discussion:** H. ENGMAN presented a review of the administrative technical and grammatical changes to 247 CMR 20.00 Reporting.

H. ENGMAN will try to remove/change all references to 247 CMR 17.00 since that section does not yet exist.

**Action:** Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to adopt the changes and move forward with promulgation.

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**5. 247 CMR 13.00 Registration Requirements And Minimal Professional Standards For Nuclear Pharmacies**

**Time: 9:35 AM**

**Presented by:** M. CHAN and W. FRISCH

**Recusal:** None

**Discussion:** W. FRISCH provided background information on the history of the revisions to 247 CMR 13.00 including meeting with nuclear pharmacy stakeholders. Board staff reviewed the NABP model act also engaged the DPH Radiation Control Program for their comments. The MA Radiation Control Program focuses on radiation safety and materials control and not the practice of pharmacy. Board staff has suggested many edits including language for a non-resident nuclear pharmacy licensing category which is not part of the proposed 247 CMR 6.00.

Edits also require nuclear pharmacies to adhere to USP <825> that deals with radiopharmaceuticals preparation, compounding, dispensing, and repackaging. This chapter was developed specifically for nuclear pharmacy practice and encompasses pertinent provisions from USP <797> and USP <795>. Since USP <825> is intended to stand on its own, it is proposed that nuclear pharmacies be exempt from 247 CMR 17, 18, 19, once promulgated.

M. CHAN then led an item-by-item review of the draft of 247 CMR 13.00.

**Action:** Motioned by A. STEIN, seconded by T. FENSKY, and voted unanimously by those present to advance the draft regulation for administrative review and a second public comment period.

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**TOPIC VIII****FILE REVIEW**

Case #1

SA-INV-15665

Walgreens #3135, DS2289

Time: 9:56 AM

RECUSAL: S. HAMILTON, M. GODEK and T. FENSKY recused and were not present for the discussion or vote in this matter.

DISCUSSION: Intern H. PATEL presented and summarized the investigative report that pertained to these matters.

- Complaint filed for refusal to transfer prescriptions as requested by the patient.
- On October 9, 2019, MOR Barakat responded that a BMC pharmacist called the pharmacy to transfer a regular patient's prescription profile. MOR Barakat reached out to the patient to inquire if her staff had caused her to leave and the patient's physician informed her that the patient should sign up for an internal program and the BMC pharmacist would reach out to the patient to give her details about the program.
- On October 9, 2019 at 4pm, MOR Barakat noted that a staff member at BMC pharmacy called again to request a transfer of this patient's prescription and MOR Barakat informed the pharmacist that the patient requested to stay at Walgreens.
- MOR Barakat noted that the BMC pharmacist indicated that she was blocking patient care. There was no delay in treatment as the patient had just received medications. Transfer request was for the following month's fill.
- The patient provided a statement indicating that she would like to stay at Walgreens Pharmacy.

ACTION: Motion by P. GANNON, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-15665), No Violation.

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Case #2

SA-INV-15664

Walgreens #9152, DS3515

Time: 9:58 AM

RECUSAL: M. GODEK recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Complaint received on 10/9/19 from a Physician that the Pharmacy could not locate the Patient's prescriptions for #30 amphetamine salts 20 mg tablets issued electronically on 9/4/19 with "earliest fill dates" of 10/4/19 and 11/3/19 that showed "Status Verified" in her record.
- Pharmacist Patel investigated the issue and claimed the prescriptions for 10/4/19 and 11/3/19 were not received. The Physician's office was contacted multiple times for a new prescription in October. Despite explaining the medication could not be dispensed without a valid prescription, the Office Manager initially refused to resend the prescription stating the pharmacy had to find the lost hardcopy. After the Patient contacted the Physician's office, a new prescription was issued on 10/8/19.
- Supervisor DeLeo confirmed that this is currently a technology issue at the Pharmacy where a prescription with a "to be filled on" a future date cannot be stored then activated on that future date.

Contrary to Supervisor DeLeo's statement, Pharmacist Patel responded that the Pharmacy does receive prescriptions with "earliest fill dates" that are data entered into the patient profile and filled on a future date.

- DM Saleem confirmed with SureScripts that the Physician had sent 3 prescriptions for amphetamine salts 20 mg tablets on 9/4/19. DM Saleem determined that CPhT Vargas inappropriately deleted 2 of 3 prescriptions received from the computer system instead of storing them to the patient profile.
- CA: An enhancement was implemented chain-wide the week of 12/15/2019 detailing the updated process for handling prescriptions, including those for CIIIs, with a "Do Not Dispense Before Date". The date is now highlighted in yellow to help pharmacy team members identify that the prescription is not a duplicate but is a prescription with a future effective date. Pharmacist Patel and CPhT Vargas attested to reviewing 247 CMR 15 in its entirety.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to CLOSE the matter (SA-INV-15664), Discipline Not Warranted, Remediation Complete.

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Case #3

PHA-2019-0115

Walgreens #2268, DS1901

Time: 10:01 AM

RECUSAL: M. GODEK recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- RLCS on 11/20/19 for an unknown loss of #100 oxycodone 5 mg tablets discovered during the reconciliation of the perpetual inventory on 11/6/19.
- Internal investigation included search of the entire pharmacy for the bottle including the safe, all trash receptacles including the dumpster, the HIPAA trash bins, and the waiting bins; reconciliation of purchase invoices and DEA 222 forms with the perpetual inventory; and all oxycodone 5 mg tablet prescriptions dispensed since the prior reconciliation were researched in case of a computer error. Security footage of the processing, dispensing, and handling of oxycodone 5mg tablets was reviewed with "no significant evidence of pilferage could be ascertained from the video". Patients who had been dispensed oxycodone 5mg tablets since the prior reconciliation were contacted and all denied over-dispensing.
- According to MOR Poe, "The medication may have been thrown out, given in excess to a patient, lost or stolen".
- CA: the pharmacist on duty will perform and log a daily count of all oxycodone 5 mg tablets for 3 months; only the pharmacist will be allowed to count CIIIs for patients or inventory counts; all CIIIs will be back-counted by the pharmacist after dispensing; the CII safe will be locked at all times including when CIIIs are counted or handled by the pharmacist; while waiting for the timed-safe to open, all CIIIs will be kept in the direct line of vision of the pharmacist in front of the computer monitor; only the open bottle of oxycodone 5 mg tablets will have a cap; all other bottles of oxycodone 5 mg tablets will not have a cap so the pharmacist can readily identify the unopened bottles in the safe.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to refer the matter (PHA-2019-0115) to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #4

PHA-2019-0113

Rite Aid #10206, DS2412

Time: 10:04 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Untimely, incomplete RLCS on 11/11/19 for an unknown loss of #132 tramadol 50 mg tablets discovered on or about 9/26/19. The required information per Appendix I of Board Policy 2018-05 was not submitted.
- MOR Bean indicated that she was aware of a discrepancy in the monthly cycle counts in August 2019 and October 2019 and did not report the loss to the district leader because she thought they were just misplaced. She indicated that she found the lost bottles but by the time she fixed the inventory, the district leader had started an investigation. The investigation concluded there was no active theft or diversion.
- CA: The pharmacy team will double count all controlled substances and the pharmacist will verify with the appropriate back-counts. The store pharmacists were retrained on the controlled substance policies to ensure compliance. MOR Bean indicated that she reviewed Rite Aid Policy "Controlled Substance Loss (Reporting & Compliance) with the district leader and was informed any controlled substance loss must be reported.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present (Note: S. HAMILTON was not present for the vote), to DISMISS the matter (PHA-2019-0113), No Violation.

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Case #5

PHA-2019-0112

Stop & Shop #20, DS2669

Time: 10:06 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Untimely RLCS on 11/18/19 for an unknown loss of #53 methylphenidate 10 mg tablets discovered on 10/12/19 by Pharmacist Dockray but not reported until MOR Nguyen was reconciling the perpetual inventory on 10/20/19. A DEA 106 was not filed with the DEA.\
- Internal investigation included a reconciliation of DEA 222 forms and purchase invoices against the perpetual inventory, review of cycle counts, biennial inventory, dispensing reports and staffing schedules to identify all staff, including floaters or temporary staff, who had access to the pharmacy at the time of the loss. Security camera footage was reviewed but was inconclusive. MOR Nguyen confirmed that the one patient who was dispensed methylphenidate 10 mg tablets since the last reconciliation was contacted and did not report an over-dispense.

- Although the cause of the loss could not be determined, MOR Nguyen suspected he inadvertently discarded the medication in the trash after filling the last prescription on 10/9/19.
- CA: MOR Nguyen reviewed policies and procedures related to the Schedule II perpetual inventory and the handling of controlled substances with all pharmacy staff. A special emphasis was placed on prompt communication of any discrepancies as well as the importance of maintaining accurate inventories.

ACTION: Motion by S. HERNANDEZ, seconded by A. STEIN, and voted unanimously by those present, to refer the matter (PHA-2019-0112) to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #6

PHA-2019-0106

Eaton Apothecary #2300, DS89842

Time: 10:11 AM

RECUSAL: Intern H. PATEL recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Inspectional deficiencies for supervisory ratios from a retail compliance inspection (ISP-13296) conducted on 10/4/19 for 1 pharmacist, 3 PTs, 1 cashier;
- Initial POC submitted was inaccurate stating the Pharmacy was in ratio at the time of inspection with 1 pharmacist, 2 PTs with 1 PT as a cashier;
- Only support staff schedules and the pharmacists' schedules were provided in response to the complaint despite numerous requests. A review of the schedules identified 37 occasions (29 days out of 54 days) from 10/07/2019 to 12/21/2019 when the Pharmacy was out of ratio for at least 1-2 hours daily when only one pharmacist was scheduled.
- MOR Nogarotto stated CPhT Crespo performs the scheduling of the pharmacy support staff (which is reflected on the schedules).
- CA: POC provided on 12/2/19 stated all staff pharmacists have been instructed to ensure that when PTs are scheduled as cashiers that they do not perform any PT duties. Support personnel will be scheduled in a manner that does not exceed the allowed ratios. The schedule will be inspected weekly by the MOR to make sure that all days are scheduled with the appropriate ratio.

ACTION: Motion by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0106), No Discipline Warranted, Remediation Complete.

**Topic IX**

**EXECUTIVE SESSION**

**Time: 10:15 AM**

**Read by K. Tanzer**

DISCUSSION:

ACTION: At 10:15 AM President K. Tanzer read the statement on reasons for Executive Session.

**Topic IX:**

**Executive Session Call to Order:**

**Time: 11:31 AM**

By: K. Tanzer

ACTION: Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by roll call to call the 2/6/20 meeting of the Executive Session to order.

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; A. Stein, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; T. Fensky, yes; R. Lopez, yes.

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**Topic X:    Adjudicatory Session (M.G.L. ch 30A § 18)                          Time: 10:17 AM**

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter Adjudicatory Session.

At 10:17 AM, A. Stein seconded by P. Gannon and voted unanimously by all those present to enter Adjudicatory Session:

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**Topic XI:    M.G.L. 65 C #1    Time: 10:25 AM**

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 10:25 AM P. Gannon, seconded by T. Fensky and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

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**Topic XII    ADJOURNMENT OF MEETING    TIME: 2:34 PM**

ACTION: Motion by P. Gannon seconded by T. Fensky, and voted unanimously by those present, to adjourn from General Session.

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 2/6/20 General Session
2. Draft Minutes of the 1/9/20 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on PSUD 17-03
8. Applications: Genoa Healthcare/Milford New Community Pharmacy
9. Applications: ETHOS Veterinary Health; DS90035 Renovation
10. Applications: Bravo Pharmacy; DS89981 Renovation
11. Applications: Winn Pharmacy New Community Pharmacy

12. Applications: Roula Barada; PH232382 Reactivation of Pharmacist License
13. Applications: Williamstown Apothecary New Community Pharmacy
14. Applications: Walmart Pharmacy 10-2366 Change of Manager
15. Policy 2020-01 Pharmacist License Reactivation after Expiration beyond one renewal cycle
16. Policy 2020-02: Compounding of Commercially Available Drugs
17. Staff Action Policy 13-01: Licensure Applications and Notices
18. 247 CMR 6.00 Licensure of Pharmacies
19. 247 CMR 9.00 Professional Practice Standards
20. 247 CMR 15.00 Continuous Quality Improvement Program
21. 247 CMR 20.00 Reporting
22. 247 CMR 13.00 Registration requirements and minimal professional standards for nuclear pharmacies
23. SA-INV-15665 Walgreens #3135 DS2289
24. SA-INV-15664 Walgreens #9152 DS3515
25. PHA-2019-0015 Walgreens #2268 DS1901
26. PHA-2019-0013 Rite Aid #10206 DS2412
27. PHA-2019-0012 Stop & Shop #20 DS2669
28. PHA-2019-0106 Eaton Apothecary #2300 DS89842

Respectfully Submitted,  
Leah Giambarresi, PharmD, RPh, Secretary